

Xylometazoline Hydrochloride Nasal Solution

DEFINITION
Xylometazoline Hydrochloride Nasal Solution is an isotonic solution of Xylometazoline Hydrochloride in water. It contains NLT 90.0% and NMT 110.0% of the labeled amount of xylometazoline hydrochloride ($C_{16}H_{24}N_2 \cdot HCl$).

IDENTIFICATION
Change to read:
• **A.** ▲The UV spectrum of the xylometazoline peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2019)
Add the following:
▲• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2019)

ASSAY
Change to read:
• **PROCEDURE**
▲**Solution A:** 1.4 g/L of [monobasic potassium phosphate](#). Adjust with [phosphoric acid](#) to a pH of 3.0.
Solution B: Acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
5	70	30
20	15	85
35	15	85
37	70	30
45	70	30

System suitability solution: 0.01 mg/mL each of [USP Xylometazoline Hydrochloride RS](#) and [USP Xylometazoline Related Compound A RS](#) in [water](#)
Standard solution: 0.05 mg/mL of [USP Xylometazoline Hydrochloride RS](#) in [water](#)
Sample solution: Nominally 0.05 mg/mL of xylometazoline hydrochloride from a suitable volume of Nasal Solution in [water](#)
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: LC
Detector: UV 220 nm. For *Identification A*, use a diode array detector in the range of 210–300 nm.
Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times are given in [Table 2](#).]

Suitability requirements

Resolution: NLT 2.0 between xylometazoline related compound A and xylometazoline, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of xylometazoline hydrochloride ($C_{16}H_{24}N_2 \cdot HCl$) in the portion of Nasal Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of xylometazoline from the *Sample solution*

r_S = peak response of xylometazoline from the *Standard solution*

C_S = concentration of [USP Xylometazoline Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of xylometazoline hydrochloride in the *Sample solution* (mg/mL)

▲ (USP 1-Aug-2019)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

Add the following:

▲ • ORGANIC IMPURITIES

Solution A, Solution B, Mobile phase, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 0.001 mg/mL of [USP Xylometazoline Hydrochloride RS](#) in [water](#)

Sensitivity solution: 0.5 µg/mL of [USP Xylometazoline Hydrochloride RS](#) from the *Standard solution* in [water](#)

Sample solution: Nominally 0.5 mg/mL of xylometazoline hydrochloride from a suitable volume of Nasal Solution in [water](#)

System suitability

Samples: *System suitability solution*, *Standard solution*, and *Sensitivity solution*

[NOTE—The relative retention times are given in [Table 2](#).]

Suitability requirements

Resolution: NLT 2.0 between xylometazoline related compound A and xylometazoline, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Nasal Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each degradation product from the *Sample solution*

r_S = peak response of xylometazoline from the *Standard solution*

C_S = concentration of [USP Xylometazoline Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of xylometazoline hydrochloride in the *Sample solution* (mg/mL)

F = relative response factor for the corresponding degradation product (see [Table 2](#))

Acceptance criteria: See [Table 2](#). The reporting threshold is 0.10%.

Table 2